

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: Ferree

Serial No.: 10/652,842

Group No.: 3738

Filed: August 29, 2003

Examiner: S. Jackson

For: CEMENTED ARTIFICIAL DISC REPLACEMENTS

APPELLANT'S CORRECTED APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party in interest in this case is Dr. Bret A. Ferree, Applicant and Appellant.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 33 claims. Claims 17, 18 and 26 have been canceled. Claims 1-16, 19, 27, 28, 30, 32 and 33 have been withdrawn from consideration. Claims 1-16, 19-25 and 27-33 are pending; however, claims 20-25, 29 and 31 are rejected and under appeal. Claim 20 is the sole independent claim under appeal.

IV. Status of Amendments

No after-final amendments have been filed.

V. Summary of Claimed Subject Matter

Independent claim 20 is directed to a system including an artificial disc replacement (ADR) configured for placement within a vertebral disc space between opposing vertebral endplates, the ADR comprising a component forming a cavity between the component and one of the vertebral endplates; and a path to fill the cavity with cement after the component is installed. (Specification, page 2, lines 20-27; Figure 1B, #120; Figure 6, #602).

VI. Grounds of Rejection To Be Reviewed On Appeal

A. The rejection of claims 20-25 and 31 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,759,766 to Buettner-Janz et al. or, in the alternative, under 35 U.S.C. §103(a) as being obvious in view of U.S. Patent No. 4,759,766 to Buettner-Janz et al.

B. The rejection of claims 20-25, 29 and 31 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,759,766 to Buettner-Janz et al. in view of U.S. Patent No. 6,273,891 to Masini.

VII. Argument

A. The rejection of claims 20-25 and 31 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,759,766 to Buettner-Janz et al.

Claims 20-25 and 31 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) over Buettner-Janz et al. ('766). Claim 20 has been amended to more positively recite that the cavity formed between an ADR component and a vertebral body is filled with cement *after the component is installed*.

The Examiner argues that Buettner-Janz discloses “a component forming a cavity (at 8) between the component and one of their vertebral endplates; and a path (the channels between the 3s) is ‘fully capable’ of filling the cavity with cement,” citing column 5, lines 28-30. First of all, the space between the “3s” is not a path at all, but rather, is simply a spacing between teeth which go the way when the component is pressed into a vertebral body. The Examiner’s reference to column 5, lines 28-30 discloses that “the cavity below the plane guide rim 2 is filled with a disc 8 made of alloplastic material. It is also possible to fill this cavity with bone cement or to use a solid center portion from the outset.”

This doesn't mean that any path is created to fill any void *in-situ*. It simply states that alternate materials may be used in advance of installation to take up a certain space.

The Examiner argues that "Applicant assumes that Buettner-Janz et al cannot be considered install [sic] and still have the space between the 3s open. This is not the case Buettner-Janz is fully capable of being installed with the anchor engaging the verterba but not imbedded into the rim." (Final OA, top of p. 2) This is not what the reference says. Rather, the reference states:

"The offset edges of the end plates are provided with teeth 3, which guarantee a safe anchorage in the vertebrae bodies." (Buettner-Janz, 4:66-68)

The Examiner's suggestion that the end plates could somehow be put in wrong, then filled with cement (between two spikes) is not supported by any evidence. That Buettner-Janz et al. use the word *guarantee* in the passage above indicates that the reference does not enable "the anchor engaging the verterba but not imbedded into the rim," under §102, as the Examiner surmises. As to §103, a partial installation would run counter to the intended use set forth by the reference. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

B. The rejection of claims 20-25, 29 and 31 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,759,766 to Buettner-Janz et al. in view of U.S. Patent No. 6,273,891 to Masini.

As per claims 20, 21 and 22, the Examiner does not state why these claims is obvious over the Beuttner-Janz/Masini combination. With regard to claim 31, the Examiner references Figure 10 or 11, and also makes mention of "the channels between the 3s." However, there are no 3s in Figures 10 or 11. The Examiner also states that these "paths" are "fully capable of having cement injected between them . . ." However, since the Examiner has not given any description or example of how this would be carried out, Applicant respectfully requests how the "space" between "3s" could somehow have cement injected between them.

It appears to Appellant that the Examiner is using the Beuttner-Janz/Masini combination only for the purposes of rejecting claim 29, which adds to claim "an instrument for pressurizing the cement following introduction." The Examiner concedes that Buettner-Janz is "silent on any instruments for

placing cement, including an instrument for pressurizing the cement following introduction.” Simply because Masini discloses “another prosthetic system for a hip replacement,” the Examiner concludes that it would have been obvious to modify the prosthetic [sic] of Buettner-Janz to include the injection system as taught by Masini in order to fill and seal space between prosthetic and bone with the cement. Such a modification amounts to mere substitution of one functionally equivalent cement delivery system for another within the art of prosthetics.”

Appellant respectfully disagrees. First, there is no teaching or suggestion whatsoever from the prior art to use any kind of cement pressurization system in Buettner-Janz. Based on this alone, such a “modification” does not amount to a “mere substitution,” but rather, amounts to hindsight reasoning on the part of the Examiner. A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000)

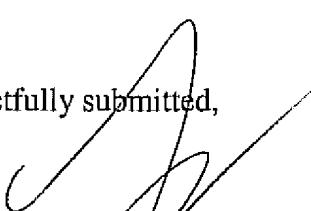
As to claim 29, the Examiner gives no specific reasons why the claim is rejected.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board’s concurrence at this time.

Respectfully submitted,

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APPENDIX ACLAIMS ON APPEAL

20. A system including an artificial disc replacement (ADR) configured for placement within a vertebral disc space between opposing vertebral endplates, the ADR comprising:
a component forming a cavity between the component and one of the vertebral endplates; and
a path to fill the cavity with cement after the component is installed.
21. The system of claim 20, wherein the path is formed in the component.
22. The system of claim 20, wherein the path is a channel or groove.
23. The system of claim 20, wherein the component includes a peripheral rim to form the cavity.
24. The system of claim 20, wherein the component is a rigid endplate.
25. The system of claim 20, wherein the component is polyethylene or other suitable polymeric material.
29. The system of claim 20, further including an instrument for pressurizing the cement following introduction.
31. The system of claim 20, further including two components, one proximate to each of the opposing vertebral endplates; and
paths for injecting cement between each component and its respective vertebral endplate.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.